Serial No.: 10/081,835 Filed: February 22, 2002

Page -3-

Listing of Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

- 1.-21. (Canceled)
- 22. (Currently amended) The composition according to claim [21] <u>65</u>, wherein the <u>muscle-derived</u> stem cell matrix is contractible.
- 23.-37 (Canceled)
- 38. (Currently amended) A preparation [of] <u>comprising muscle-derived</u> stem cells and a physiologically acceptable substrate material forming an implantable and innervatable <u>biomatrix comprising a two- or</u> three-dimensional scaffolding for tissue and organ <u>treatment or</u> repair.
- 39. (Previously presented) The preparation according to claim 38, wherein the substrate material is small intestine submucosa (SIS).
- 40. (Currently amended) The preparation according to claim 38, wherein the <u>muscle-derived</u> stem cells are autologous to a recipient of the preparation.
- 41. (Currently amended) The preparation according to claim 38, wherein the <u>muscle-derived</u> stem cells are allogeneic to a recipient of the preparation <u>and reduction or alleviation</u> of an immune response by the recipient comprises one of more of (i) histocompatability between the stem cells and the recipient; (ii) recipient immunosuppression therapy; (iii) recipient immunomodulatory therapy; or (iv) recipient immunological tolerance.
- 42. (Canceled)
- 43. (Currently amended) The preparation according to claim 38, wherein the <u>muscle-derived</u> stem cells are <u>obtained derived</u> from skeletal muscle.
- 44. (Currently amended) The preparation according to elaim 42 or claim 38 or claim 43, comprising a three-dimensional muscle replacement having muscle contractility.

Express Mail Label No.: EL991158297 US

Docket No.: <u>28682-502</u> (Formerly 2710-4011-US1)

Serial No.: 10/081,835 Filed: February 22, 2002

Page -4-

45. (Currently amended) The preparation according to claim 44, further wherein the substrate material is small intestine submucosa (SIS).

46.-63 (Canceled)

- (New) The preparation according to claim 38, wherein the muscle-derived stem cell 64. matrix is contractible.
- (New) A composition comprising muscle-derived stem cells and a physiologically 65. acceptable matrix material admixed to form a muscle-derived stem cell biomatrix, said musclederived stem cells being incubated with said physiologically acceptable matrix material in vitro for less than about 12 hours prior to use.
- 66. (New) The composition according to claim 65, wherein the matrix material is selected from the group consisting of small intestine submucosa (SIS), crosslinked alginate, bioadhesives, hydrocolloid, collagen gel, collagen sponge, polyglycolic acid (PGA) mesh, polyglactin (PGL) mesh, fleeces and dead de-epidermized skin equivalents in one or more layers.
- 67. (New) The composition according to claim 66, wherein the matrix material comprises small intestine submucosa (SIS).
- 68. (New) The composition according to claim 65, wherein the matrix material is absorbable or non-absorbable.
- 69. (New) The composition according to claim 65, wherein homogeneous or heterogeneous populations of muscle-derived stem cells are admixed with the matrix material.
- 70. (New) The composition according to claim 65, wherein the muscle-derived stem cell matrix is contractible.
- (New) The composition according to claim 65, wherein the matrix material comprises 71. from about 2.5 x 10^3 to about 1 x 10^6 muscle-derived stem cells.

Express Mail Label No.: EL991158297 US

Docket No.: 28682-502 (Formerly 2710-4011-US1)

Serial No.: 10/081,835 Filed: February 22, 2002

Page -5-

72. (New) The composition according to claim 71, wherein the matrix material comprises from about 5×10^3 to about 1×10^6 muscle-derived stem cells.

73. (New) The composition according to claim 65, wherein the matrix material comprises about 1 x 10⁵ muscle-derived stem cells per 1 cm² of matrix.

74. (New) The composition according to claim 65, wherein the muscle-derived stem cells are incubated with the matrix material *in vitro* for less than about 3 hours prior to use.

75. (New) The composition according to claim 65, wherein the muscle-derived stem cells are incubated with the matrix material *in vitro* for less than about 1 hour prior to use.

76. (New) The composition according to claim 65, wherein the muscle-derived stem cells are incubated with the matrix material *in vitro* for less than about 30 minutes prior to use.

77. (New) The composition according to claim 65, wherein the muscle-derived stem cells are incubated with the matrix material *in vitro* from about 5 seconds to about 30 minutes prior to use.

78. (New) The composition according to claim 65, wherein the muscle-derived stem cell matrix is used for tissue or organ treatment or repair.

79. (New) The composition according to claim 78, wherein the tissue or organ treatment or repair is selected from the group consisting of wound healing, surgical incision repair, tissue augmentation, organ augmentation, smooth muscle repair, non-smooth muscle repair and blood vessel repair.

80. (New) The composition according to claim 65, wherein the muscle-derived stem cells are attached to the matrix material using biological adhesives.

81. (New) The composition according to claim 65, wherein the muscle-derived stem cells alter biomechanical properties of the matrix material.

82. (New) The composition according to claim 81, wherein the muscle-derived stem cell-matrix forms 2-dimensional muscle tissue and organ structures.

Express Mail Label No.: EL991158297 US

Docket No.: 28682-502

(Formerly 2710-4011-US1)

Serial No.: 10/081,835 Filed: February 22, 2002

Page -6-

83. (New) The composition according to claim 81, wherein the muscle-derived stem cell-matrix forms 3-dimensional muscle tissue and organ structures.

- 84. (New) The composition according to claim 65, wherein the muscle-derived stem cell-matrix material comprises a form selected from a sling, patch, or wrap.
- 85. (New) The composition according to claim 65, wherein the muscle-derived stem cell matrix material comprises a physiologically compatible adhesive.
- 86. (New) A preparation comprising autologous muscle-derived stem cells and a physiologically acceptable substrate material forming an implantable and innervatable biomatrix comprising a two- or three-dimensional scaffolding for tissue and organ treatment or repair.
- 87. (New) A composition comprising autologous muscle-derived stem cells and a physiologically acceptable matrix material admixed to form a muscle-derived stem cell biomatrix, said autologous muscle-derived stem cells being incubated with said physiologically acceptable matrix material *in vitro* for less than about 12 hours prior to use.
- 88. (New) The preparation according to claim 38 or claim 86, wherein the biomatrix is used in the treatment or repair of one or more of smooth muscle, skeletal muscle, skin, connective tissue, bladder, sphincter, or blood vessels.
- 89. (New) The composition according to claim 65 or claim 87, wherein the musclederived stem cell matrix is used in the treatment or repair of one or more of smooth muscle, skeletal muscle, skin, connective tissue, bladder, sphincter, or blood vessels.
- 90. (New) A muscle-derived stem cell biomatrix comprising muscle derived stem cells and a physiologically acceptable substrate material forming an implantable and innervatable biomatrix comprising a two- or three-dimensional scaffolding for tissue and organ treatment or repair, said muscle-derived stem cells being incubated with said physiologically acceptable substrate material *in vitro* for less than about 12 hours prior to use.

Express Mail Label No.: EL991158297 US

Docket No.: 28682-502

(Formerly 2710-4011-US1)

Serial No.: 10/081,835 Filed: February 22, 2002

Page -7-

91. (New) A muscle-derived stem cell biomatrix comprising autologous muscle derived stem cells and a physiologically acceptable substrate material forming an implantable and innervatable biomatrix comprising a two- or three-dimensional scaffolding for tissue and organ treatment or repair, said autologous muscle-derived stem cells being incubated with said physiologically acceptable substrate material *in vitro* for less than about 12 hours prior to use.

92. (New) The biomatrix according to claim 90 or claim 91, wherein the muscle-derived stem cell matrix is used in the treatment or repair of one or more of smooth muscle, skeletal muscle, skin, connective tissue, bladder, sphincter, or blood vessels.

Express Mail Label No.: EL991158297 US

Docket No.: 28682-502

(Formerly 2710-4011-US1)